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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/314,889 | 05/19/1999 | GUO-LIANG YU | 1488.0310006 | 5766 |

22195 7590 09/03/2003

HUMAN GENOME SCIENCES INC
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EXAMINER

ULM, JOHN D

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1646

DATE MAILED: 09/03/2003

34

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/314,889

Applicant(s)

YU ET AL.

Examiner

John D. Ulm

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 05 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 27-56 and 102-219 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 122-129, 131-138, 140-147, 149-156, 158-165 and 167-175 is/are allowed.
- 6) ☐ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) 29, 30, 33, 34, 48, 177, 178, 188, 189, 199, 200, 210 and 211 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 28.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims rejected are 27,28,31,32,35-47,49-56,102-121,130,139,148,157,166,175,176,179-187,190-198,201-209 and 212-219.

1) Claims 27 to 56 and 102 to 219 are pending in the instant application. Claims 57 to 101 have been canceled and claims 122 to 219 have been added as requested by Applicant in Paper Number 27, filed 07 November of 2002.

2) Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.



3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4) The declaration by Thi-San Migone that was filed on 21 November of 2002 under 37 CFR 1.132 is sufficient to overcome the rejection of claims 27 to 56 and 102 to 121 based upon lack of utility. The explanation contained therein of the relevance of the activation of the NF- B transcription factor by the protein encoded by the claimed nucleic acid, when agonist activated, in view of the disclosure in lines 20 to 24 on page 46 of the instant specification that NF- B activation is pro-inflammatory supports the apparently contradictory assertions in the specification that an agonist to the claimed protein can induce apoptosis whereas an antagonists thereto can be anti-inflammatory. Therefore, the assertion on page 46 of the instant specification that the protein of the instant invention can be employed to identify antagonists thereto, which would be expected to be anti-inflammatory, constitutes a credible, specific and substantial utility. However, the utility of a protein encoded by a nucleic acid of the instant invention in the identification of agonists and antagonists thereto is limited to a protein that provides an authentic response, which is predictive of an *in vivo* physiological response. This declaration does not support a specific and substantial utility for an isolated nucleic acid

encoding all or a portion of a protein that does not provide an authentic response because the information derived therefrom would have no immediate practical utility.

5) Claims 122 to 129, 131 to 138, 140 to 147, 149 to 156, 158 to 165 and 167 to 175 are allowable as written.

6) Claims 27, 28, 31, 32, 35 to 47, 49 to 56, 102 to 121, 176, 179 to 187, 190 to 198, 201 to 209 and 212 to 219 are rejected under 35 U.S.C. 112, first paragraph, because the instant specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. These claims encompass an isolated nucleic acid encoding a protein or polypeptide which is encoded by a nucleic acid that hybridizes to a reference nucleic acid under specified conditions or which has a specified degree of sequence similarity to all or a specified portion of SE ID NO:2. The instant specification discloses that the polypeptide encoded by the claimed nucleic acid can be employed to identify agonists and antagonists thereto. The information derived from the claimed polypeptide is only relevant in so far as it is predictive of the action of a compound on a native human protein. The only protein which is described in the instant specification that could reasonably be expected to behave in a manner that is predictive of a native human receptor protein is a protein comprising the complete amino acid sequence presented in SEQ ID NO:2. An isolated nucleic acid encoding only a specified portion of that amino acid sequence is only disclosed as useful in so far as it can be used to produce the polypeptide encoded thereby, which has specific practical utility in the production of antibodies to the native protein. Whereas one could readily make any one of the tens of thousands of material embodiments encompassed by the claims, one



would not expect the majority of those material embodiments to encode a protein which can function in a manner that is representative of an authentic human receptor protein.

In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that

"Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved."

Art Unit: 1646

Because the instant specification does not identify those amino acid residues in SEQ ID NO:2 of the instant specification which are critical to the structural and functional integrity of a receptor protein comprising that sequence, identify a structurally analogous protein for which this information is known and could be applied to the instant protein by extrapolation, or even provide a single working example of an isolated nucleic acid encoding an intentionally modified protein of the instant invention, much less a representative number of claimed embodiments, an artisan can not change even a single residue within the amino acid sequence of SEQ ID NO:2 and predict the effects of that change on the performance of that protein "by resort to known scientific law".

7) Claims 130, 139, 148, 157, 166, 175, 186, 197, 208 and 219 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are vague and indefinite because the identity of the polypeptide being produced by the claimed method is unclear. The act of culturing a host cell inherently results in the production of thousands of different polypeptides.

8) Claims 29, 30, 33, 34, 48, 177, 178, 188, 189, 199, 200, 210 and 211 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9) Applicant's arguments filed 07 November of 2002 have been fully considered but they are not persuasive.

Art Unit: 1646

10) Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


JOHN ULM
PRIMARY EXAMINER
GROUP 1800